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(19) World Intellectual Property Organization
International Bureau(43) International Publication Date
29 August 2002 (29.08.2002)

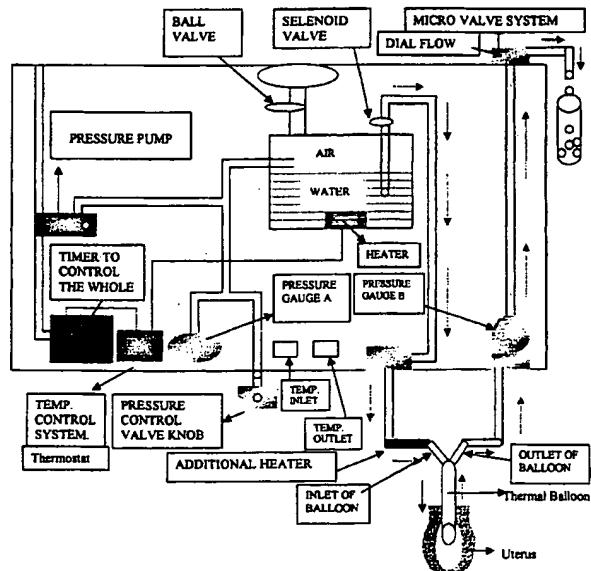
PCT

(10) International Publication Number
WO 02/065930 A1

(51) International Patent Classification⁷: A61B 18/04 (71) Applicant and
 (21) International Application Number: PCT/IB02/00381 (72) Inventor: SHAH, Tushar, Navneetlal [IN/IN]; 19, Jawa-
 (22) International Filing Date: 31 January 2002 (31.01.2002) (81) Designated States (national): AE, AG, AL, AM, AT, AU,
 (25) Filing Language: English AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,
 (26) Publication Language: English CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH,
 (30) Priority Data: 154/MUMBAL/2001 9 February 2001 (09.02.2001) IN (84) Designated States (regional): ARIPO patent (GH, GM,
 154/MUMBAL/2001 9 February 2001 (09.02.2001) IN (84) Designated States (regional): ARIPO patent (GH, GM,
 KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),

[Continued on next page]

(54) Title: APPARATUS FOR ENDOMETRIAL ABLATION



material which can withstand temperature up to 100 °C and has a capacity to store around 200ml fluid/water. Accordingly, the subject invention relates to a device to be used in the thermal ablation for the treatment of menorrhagia, comprising thermomat and thermal balloon. Thermomat consists for water container having level sensor and temperature sensor, a heater connected with said water container, a temperature controller connected to said heater, temperature display means connected with said heater at the input and output of said balloon, a pressure pump connected with said water container, a pressure control valve connected with said pressure pump and said water container, at least a pair of pressure gauges connected with the pressure pump and the outlet of the said thermal balloon, a timer connected with pressure pump, a valve provided at the outlet of the water container, a tube having its one end connected with said thermal balloon through a adopter and its other end plurality of temperature sensors in the said tube near the inlet and outlet of said balloon, a pressure gauge connected with said tube to display the intra- balloon pressure, an additional/compensatory heater connected at the terminal end of said tube before said adopter to compensate the heat loss which occurs during transit of water

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[Continued on next page]



European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

Published:

— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

from said vessel to said balloon, a temperature sensor provided at the inlet of the said thermal balloon. The thermal balloon is introduced through a cervical canal in to uterine cavity. Both the channels of the balloon are attached with the adopter of thermomat. Now balloon is inflated with heated water at fixed intrauterine pressure and temperature. There is a continuous flow of heated water through the thermal balloon which is kept for around 12 to 15 minutes after that balloon is deflated and removed from uterine cavity. The case study is connected at various centers, which show around 95 % cure rate from menorrhoea.

Apparatus for Endometrial Ablation

The present invention relates to a device to carry out Thermal Ablation for the treatment of menorrhagia.

Background:

One of the major health problems, faced by the middle-aged women is heavy menstrual cycle. It may be in the form of prolonged, excessive and / or short cycle. The incidence of this problem amongst the middle-aged women is 15-20%.

Conventionally hysterectomy (removal of uterus) is performed to control the haemorrhage. It is considered as an effective and time - tested solution. However, as hysterectomy is a major surgery, it does carry a significant morbidity, a few mortalities and more expenditure in terms of money, material and manpower. Because of these draw backs many attempts have made to find out an alternate. Endometrial ablation has emerged out as the easiest solution.

Endometrial ablation is a technique of removal of endometrium i.e., inner most layer of uterus which is responsible for bleeding. It is done through vagina and cervical opening (which is a passage of bleeding) so there is no scar in vagina or over the abdomen during process of endometrial ablation. Thus, endometrial ablation comes out as an efficient and effective technique with minimum cost, morbidity and hospital stay.

Endometrial ablation, may be conducted in a number of manner by using different techniques such as

- TCRE,
- Radio Frequency Probe,
- Hysteroscopic Laser ablation,
- Micro wave ablation,
- Thermal balloon ablation and
- Hydrothermal ablation.

However, amongst all these techniques, thermal balloon ablation has found to be most successful.

Thermal balloon ablation is a technique where a specially designed balloon is passed through vagina in to uterine cavity. Hot water is passed through a balloon at fixed temperature (around 85 C) at control pressure (200-250mmHg) for duration of 10 to 15 minutes. This procedure ensures removal of endometrial tissue by heat necrosis. Because of removal of endometrium it would control uterine bleeding. On this account, the thermal balloon has developed in to a simple, effective and economical method.

A device to carry out thermal balloon ablation, which is available and known in the field is faced with certain disadvantages. In the conventionally available devices used in thermal ablation a small heater, pressure and temperature sensors are placed inside the balloon itself. The balloon is

inserted inside the uterine cavity and is inflated with cold water to create fixed intrauterine pressure of around 200mmHg. The heater inside the balloon is started and temperature of 86 C is achieved and maintained for prefixed period and then balloon is deflated and removed. The major disadvantage found in this device is that the heater is provided in the balloon and electric current is passed inside the body. The balloon is disposable after only one use and is very expensive. The device of subject application has been successfully devised to overcome these problems. In the present device, the thermal balloon is not having any heater, temperature or pressure sensors. The water is heated outside the body and is circulated continuously in the balloon giving heat to the endometrium by keeping fixed intra-uterine pressure and temperature and no current is passed inside the body.

Hence, present invention is in respect to a device used in thermal ablation to cure menorrhoea (heavy menstrual bleeding).

The subject device comprises a machine, preferably an electronic machine to pass hot water at controlled temperature and pressure in the inflated balloon in the uterine cavity. The balloon is insufflated with heated water at fixed intrauterine pressure and temperature at desired level.

The balloon used in the subject application is a specially designed balloon, which is a blind ended catheter with balloon at the top of it. The balloon is made up of latex material which can withstand temperature upto 100 C and has a capacity to store around 200ml of fluid/water.

Accordingly, the subject invention relates to a device to be used in the thermal ablation for the treatment of menorrhoea, comprising thermomat and thermal balloon connected with the said thermomat, wherein the said thermomat consists of water container having level sensor and temperature sensor, a heater connected with said water container, a temperature controller connected to said heater, temperature display means connected with said heater at the input and output of said balloon, a pressure pump connected with said water container, a pressure control valve connected with said pressure pump and said water container, atleast a pair of pressure gauges connected with the pressure pump and the outlet of the said thermal balloon, a timer connected with pressure pump, a valve provided at the outlet of the water container, a tube having its one end connected with said thermal balloon through a adaptor and its other end connected with a dial flow to control the outflow of water from the balloon provided with a plurality of temperature sensors in the said tube near the inlet and outlet of said balloon, a pressure gauge connected with said tube to display the intra balloon pressure, an additional / compensatory heater connected at the terminal end of said tube before said adaptor to compensate the heat loss which occurs during transit of water from said vessel to said balloon, a temperature sensor provided at the inlet of the said thermal balloon. The subject application may better be understood with reference to the accompanying drawings which are for illustrative purposes and should not be construed to restrict the scope of the application.

Brief Description of the accompanying drawing Figure 1 : relates to the flow chart of the subject device exhibiting the working of the said device. Figure 2 : relates to the flow chart indicating various parts of the said article.

Figure 3

Detailed description of the invention

The subject device consists of two major components

- (1) Thermomat, and
- (2) Uterine Thermal Balloon

THERMOMAT

The thermomat is an electronic machine, which passes the hot water at controlled temperature and controlled pressure in the inflated balloon in the uterine cavity. It insufflates the balloon with heated water at a fixed intrauterine pressure and fixed temperature as per desired level. The thermomat consists of various components. The body of thermomat is made up of either steel or fibre having opening in the side walls to reduce excessive heat in the body of thermomat.

The thermomat comprises of a water container which is made up of any metal, fiber or like material preferably steel. The container is provided with a ball valve at the roof over container, which connects inlet to the container for water. Different level sensors are provided in the container to display water level on the front board of the body of device. Heater is provided inside the vessel which is fixed at the base of the said vessel. It is connected to thermostat control mechanism. It heats the water at a predetermined fixed temperature and it maintains the desired level of temperature. The heater in the system is outside the water container and remains away from the body of the patient, hence is very safe. The temperature sensor is provided in the water container which very ensures that as soon as temperature reaches to desired level (which is fed as per requirement) the heater is cut off. A compensatory / additional heater may also be provided at the terminal end of the silicon tube before adaptor. The temperature sensor is attached to the inlet of balloon. After the desired level of temperature of water is attained the heater stops working. The main function of this heater is to compensate the heat loss, which occurs during transit of water from vessel to the balloon. A temperature controller thermostat is provided to regulate the temperature in the container; in fact it maintains the balloon temperature. The desired temperature is adjusted in thermostat. The heater starts working. Once the desired level of temperature is achieved in the vessel the heater automatically cuts off. Temperature display means are provided at the input as well as output of the said balloon. These means are temperature sensors provided at the input and output of balloon. The sensors display the actual temperature of the water at both ends of balloon. The subject device is provided with a pressure pump. It is a specially designed pump, which creates air pressure above the fluid level in the vessel. It is connected to water tank through one end of Y shape tube. The other end of the tube is connected to the pressure control valve. The pressure control valve is also attached to pressure gauge. The pressure pump pushes the air above the fluid level in the container (vessel). The pressure created by the air is adjusted by knob. If the knob (pressure control valve) is opened up, more air is released out which decreases the pressure above the fluid level in the vessel. If the knob is closed, more air remains above the fluid and it pushes the water into the balloon. In short, the pressure pump pushes the water to circulate effectively in and out of balloon. There are also provided pressure gauges to measure the pressure : (a) Pressure gauge A is attached to pressure pump through Y tube- display the pressure over the fluid level in the container. (b) Pressure gauge B is attached to the outgoing channel of thermal balloon, which actually measure the total intra-balloon pressure. A timer is provided to display the time in seconds.

The predetermined time is adjusted. Timer is connected with the pump. The predetermined time for the procedure is fed in the Timer. Once the Timer is on, the pump starts working. As soon as the predetermined time is over, the pump stops automatically. A valve is provided at the outlet of the container. In case balloon burst, it blocks the flow to the balloon. It works as a protective mechanism. The valve used is preferably solenoid valve. The water tank is connected by silicon tube, which is covered with heat resistance material to prevent heat loss. The silicon tube is connected through adapter to the inlet of thermal balloon by three - way valve. The other end (outlet) of thermal balloon is attached through adaptor with other silicon tube with three-way. At the other end of outgoing silicon tube, Dial flow is attached which control the outflow of water from the balloon. The pressure gauge is also attached to this silicon tube, which displays intra balloon pressure. Two temperature sensors are kept in the silicon tube near the inlet and outlet of the balloon. These sensors will give exact idea of temperature of in going water in balloon.

UTERINE THERMAL BALLOON

Uterine thermal balloon is a specially designed blind-ended catheter with balloon at the tip of it. The balloon is made up of latex material. Heat resistant powder is added for extra strength. It can withstand the temperature up to 100 C and has a capacity of around 200-ml. The two channels, which open up in the balloon, have non-return valve at other end. There is third channel, which goes right up to the balloon, but it has, a blind end.

WORKING OF THE MODEL

Working of the device : Water is added up to about 1 litre in the water container, the thermostat is adjusted at around 90 C temperature, the heater is started once the water is heated up to 90 C, heater is automatically cut off, time is adjusted for about 900 seconds, motor is started, pressure pump pushes the air in the vessel. It creates pressure above the water level. This pressure is adjusted by pressure controlled knob(valve). This pressure above the fluid level pushes the heated water in the silicon tube attached with the water vessel, silicon tube is attached with inlet of thermal balloon through adaptor, due to water under pressure, balloon gets inflated, the balloon when inflated gets pressure from the uterus, this pressure pushes the water towards outlet of balloon, which is attached with other silicon tube, the other end of this silicon tube is connected to dial flow, which controls outgoing water, due to control of outgoing water, pressure in the balloon remains maintained, there is some loss of temperature of water upto inlet of balloon, which is compensated, by compensating heater near the inlet of balloon, which will reheat the water to desired temperature, by this system, one can maintain the pressure in the balloon up 5 PSI (250 mmHg) and temperature in the balloon up to 90 C, for a period of 10 minutes which ultimately produces heat destruction of uterine endometrium, which lead to control of haemorrhage.

Thermal balloon is introduced through cervical canal into uterine cavity. Once the balloon is placed in the uterine cavity properly, it is inflated with water. One of the channels of the balloon is attached to pressure gauge where the pressure should be reached to 350 mmHg.

The net intrauterine pressure is maintained equal to balloon pressure in the uterus minus balloon pressure outside the uterus.

Normally pressure required to inflate the balloon is about 100mmHg outside the uterus. So net intrauterine pressure is around 250 mmHg. The amount of water to raise such a pressure is not to exceed 30-40 ml in the balloon.

The balloon is attached to both the tubes of the machine. The temperature of the water tank is already raised up to 80-85 C. Timer is set for 900 seconds (approx). Pressure pump is started and the pressure is adjusted in pressure gauge with the help of pressure control valve. Initially pressure is raised up to 7 PSI. The balloon in the uterus gets inflated with hot water. The pressure in the pressure gauge at the outlet will reflect the real intrauterine pressure + intra balloon pressure. It is adjusted at 7 PSI by pressure control valve. The micro drop at the dial flow is adjusted around 250 drops per minute. The intra-balloon temperature gradually rises and the sensor at the inner and outer channel displays it. It is maintained between 80-90 C with the help of compensatory heater at the end of the inner channel. The entire circulation of the water continues (i.e., hot water is passed through the inner channel into the balloon). Balloon gets inflated. Through the outer channel water goes out through the micro-drop set) and the temperature as well as the pressure levels outside and inside are well maintained. The balloon covers the entire cavity walls and the temperature and the process results in the desire removal of the endometrium.

The procedure is carried out for 12 to 15 minutes, which is pre-determinedly fixed in the Timer. Once the time is over, the pump stops automatically, balloon is deflated and removed.

RESULTS & ANALYSIS

CASE STUDY

The thermal balloon ablation technique using the device of subject application has been successfully conducted on a number of patients at Janani Maternity Home, "Sushrusha" Navrangpura, Ahmedabad-380009 and Smt. S.C.L. Municipal Hospital, Saraspur, affiliated with K. M. School of PG Medicine & Research, Ahmedabad.

- Menstrual patterns on follow up:
 - Amenorrhoea 58%
 - Oligomenorrhoea 35%
 - Normal Menstruation 04%
 - No change (symptom persist) 03%
- Dysmenorrhoea (Painful menses)
 - No. of cases = 30
 - Relief obtained = 22

The advantages found using this device while conducting the ablation therapy is that the patients can carry out routine work from next day, no scar anywhere in body, very economical and cost effective as compared to any other method of endometrial ablation & hysterectomy. It gives rise to 95% of cure rate as well as acceptance rate by patient and can be performed in high risk groups of patients.

Hence, the device and technique invented by the applicant involves an effective process for

curing menorrhoea (acute bleeding in females especially after the age of 30 and above), where the thermal balloon is inserted in the uterus and inflated by infusion of hot water at a controlled pressure and temperature. The balloon inflates and takes the shape of the uterine cavity and burns the surrounding walls.

There by it ensures to cure the problem of incessant and heavy bleeding. The invention is well tested and is an extremely convenient, economical with minimum risk.

Further improvements and/or alterations are possible in the subject device without deviating from the scope of the application. Hence, the subject application should not be construed to restrict the scope of the invention.

CLAIM:

1. The device to be used in the thermal balloon ablation for the treatment of menorrhoea, comprising thermomat and thermal balloon connected with the said thermomat, wherein the said thermomat consists of water container having level sensor and temperature sensor, a heater connected with said water container, a temperature controller connected to said heater, temperature display means connected with said heater at the input and output of said balloon, a pressure pump connected with said water container, a pressure control valve connected with said pressure pump and said water container, at least a pair of pressure gauges connected with the pressure pump and the outlet of the said thermal balloon, a timer connected with pressure pump, a valve provided at the outlet of the water container, a tube having its one end connected with said thermal balloon through an adaptor and its other end connected with a dial flow to control the outflow of water from the balloon provided with a plurality of temperature sensors in the said tube near the inlet and outlet of said balloon, a pressure gauge connected with said tube to display the intra balloon pressure, an additional / compensatory heater connected at the terminal end of said tube before said adaptor to compensate the heat loss which occurs during transit of water from said vessel to said balloon, a temperature sensor provided at the inlet of the said thermal balloon.
2. The device as claimed in claim 1, wherein body of said thermomat is made up of metal, having opening in the side walls to reduce excessive heat in the body of said thermomat.
3. The device as claimed in claim 2, where body of said thermomat is made up of steel, fiber or like material.
4. The device as claimed in claim 1, wherein said water container is made up of steel.
5. The device as claimed in claim 1, wherein said water container is provided with a valve at the top of said container connecting inlet of the said tube with said container for water.
6. The device as claimed in claim 1, wherein said level sensors are provided to display water level in the said water container.
7. The device as claimed in claim 1, wherein said valve is solenoid valve provided at the outlet of the container.
8. The device as claimed in claim 1, wherein said tube is silicon tube covered with heat resistance material to prevent loss.
9. The device as claimed in claim 8, wherein said silicon tube is connected through adaptor to the inlet of thermal balloon by three way valve.
10. The device as claimed in claim 1, wherein said thermal balloon is provided with a blind ended catheter with balloon at its tip.
11. The device as claimed in claim 10, wherein said balloon is made up of latex material.
12. The device as claimed in claim 10, wherein said balloon is provided with a non-return valve.
13. The device as claimed in claim 10, wherein said balloon is provided with atleast two channels.
14. The device as claimed in claim 13, wherein said balloon is provided with three channels.
15. The device as claimed in claim 13, wherein said third channel has a blind end.
16. The device to be used in the thermal ablation for the treatment of menorrhoea substantially as herein before described with reference to accompanying drawings.

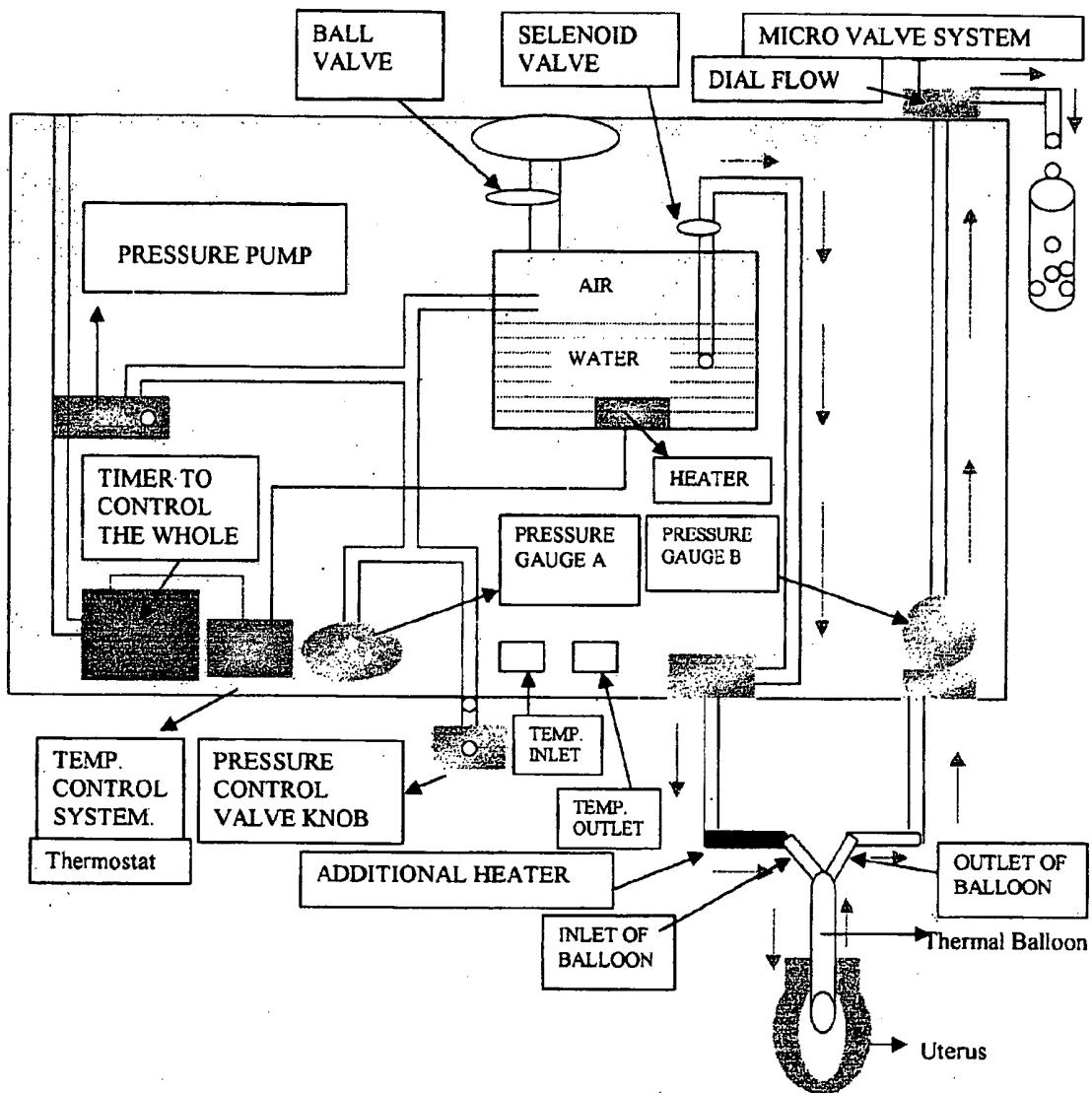


Figure. 2.

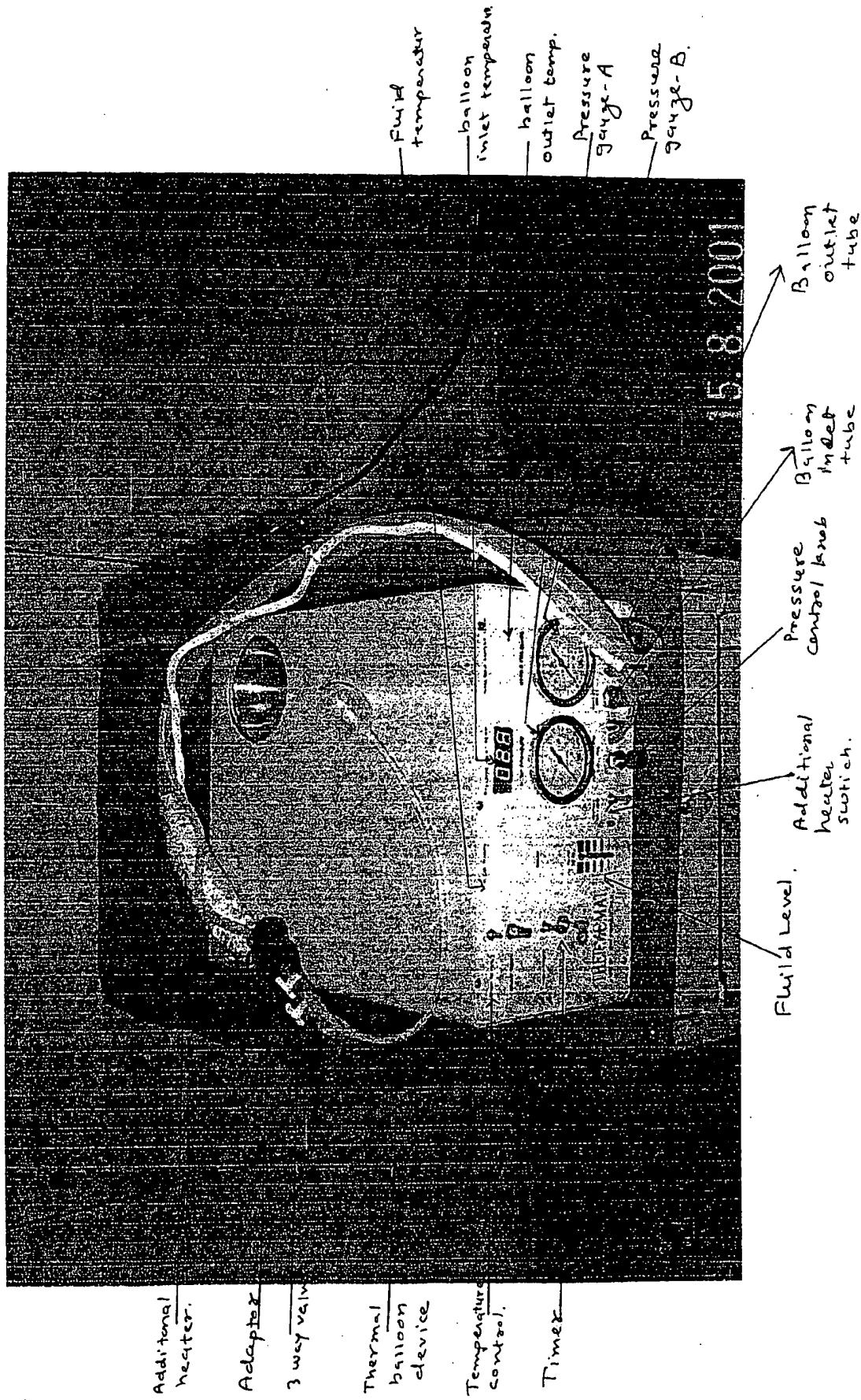
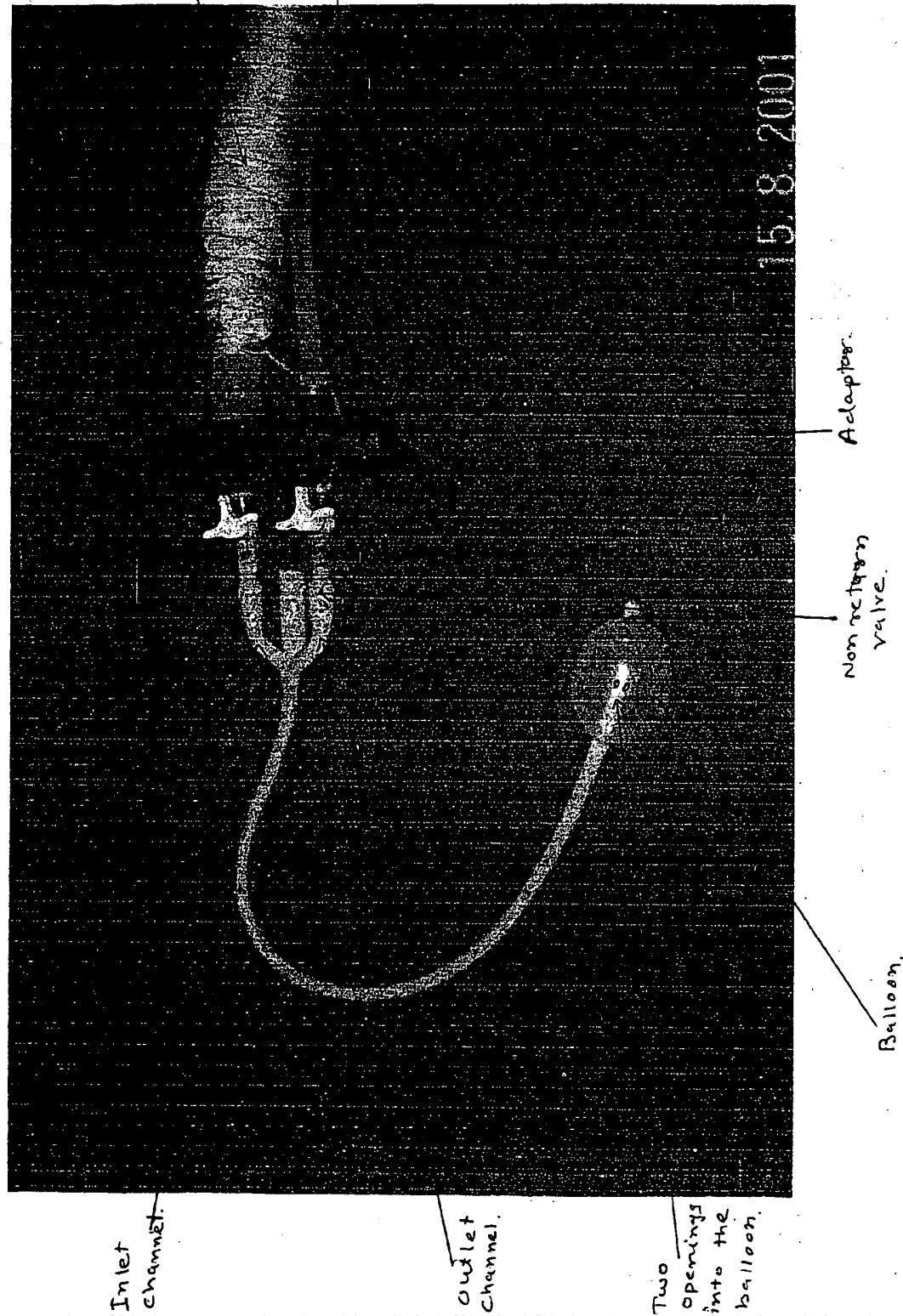
THERMOMAT WITH THERMAL BALLOON.

Figure 3.

THERMAL BALLOON WITH ADAPTER.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB 02/00381

CLASSIFICATION OF SUBJECT MATTER

IPC⁷: A61B 18/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC⁷: A61B 18/04

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 95/07664 A1 (ORIGIN) 23 March 1995 (23.03.95) <i>the whole document.</i> -----	1

Further documents are listed in the continuation of Box C.

See patent family annex.

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Date of the actual completion of the international search 19 June 2002 (19.06.2002)	Date of mailing of the international search report 28 June 2002 (28.06.2002)
Name and mailing address of the ISA/AT Austrian Patent Office Kohlmarkt 8-10; A-1014 Vienna Facsimile No. 1/53424/535	Authorized officer NÁRDAI Telephone No. 1/53424/347

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/IB 02/00381-0

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO A1 9507664	23-03-1995	US A 5449380	12-09-1995